



Patent
030639.0044.CPA2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Duft et al.

Serial No.: 08/870,762

Filed: June 6, 1997

Title: METHODS FOR TREATING OBESITY

Group Art Unit: 1645

Examiner: S. Devi

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with the Applicants' duty under 37 C.F.R. §1.56, the following information is brought to the attention of the Patent Office. Consideration of the items listed on the attached Form PTO/SB/08A is respectfully requested. For the convenience of the Patent Office, copies of these items are enclosed. Applicants request that an initialed copy of this Form be returned to Applicants, indicating that this information was considered by the Patent Office.

This Supplemental Information Disclosure Statement is being submitted under 37 C.F.R. §1.97(c)(2). Accordingly, enclosed is a check in the amount of \$180 to cover the fee due under 37 C.F.R. §1.17(p). The Commissioner is authorized to charge any additional fee required for this submission or to credit any overpayment to Deposit Account No. 50-1273.

In accordance with the requirements under 37 C.F.R. §1.98(3), enclosed is a copy of an office action from the Russian Patent Office, which pertains to a counterpart Russian patent application. The Shulutko and Starkova documents listed on the attached Form PTO/SB/08A are not in the English language, but they were cited in Russian office action. The Russian office action

CERTIFICATE OF MAILING
(37 C.F.R. §1.8(a))

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below, with sufficient postage, as First Class Mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Barbara J. Kielt
Barbara J. Kielt

June 27, 2002
Date of Deposit

includes an English-language description of the Russian Patent Office's perceived relevance of these two documents.

Respectfully Submitted,

Duft et al.

Dated: 6-27-02

By: Lisa M. McGeehan
Lisa M. McGeehan
Reg. No. 41,185

BROBECK, PHLEGER & HARRISON LLP
12390 El Camino Real
San Diego, CA 92130-2081
Phone (858) 720-2584
Fax (858) 720-2555

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	08/870,762
		Filing Date	June 6, 1997
		First Named Inventor	Bradford J. Duft
		Group Art Unit	1645
		Examiner Name	Devi, S.
		Attorney Docket Number	030639.0044.CPA2
Sheet	1	of	4

U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	U.S. Patent Document	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)	
		5,264,372		Beaumont et al.
		5,266,561		11/23/93
		5,280,014		Cooper et al.
		5,367,052		11/30/93
		5,376,638		Cooper et al.
				1/18/94
				Cooper et al.
				11/22/94
				Young et al.
				12/27/94

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		ALAM et al., "Selective Antagonism of Calcitonin-Induced Osteoclastic Quiescence (Q Effect) by Human Calcitonin Gene-Related Peptide-(Val ⁸ Phe ³⁷)," <u>Biochem. Biophys. Res. Commun.</u> , 179(1):134-139 (1991)	
		BEAUMONT et al., "Regulation of Muscle Glycogen Metabolism by CGRP and Amylin: CGRP Receptors Not Involved," <u>Br. J. Pharmacol.</u> , 115(5):713-715 (1995)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation is not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

				Application Number	08/870,762
				Filing Date	June 6, 1997
				First Named Inventor	Bradford J. Duft
				Group Art Unit	1645
				Examiner Name	Devi, S.
				Attorney Docket Number	030639.0044.CPA2
Sheet	2	of	4		

	BRAIN et al., "Amylin Amide, Which Is Structurally Similar to Calcitonin Gene-Related Peptide (CGRP), Stimulates Increased Blood Flow In Vivo," <u>Eur. J. Pharmacol.</u> , 183:2221 (1990)	
	BRAY, G.A., "Drug Treatment of Obesity," <u>Am. J. Clin. Nutr.</u> , 55:538S-544S (1992)	
	BRAY, G.A. "Treatment for Obesity: A Nutrient Balance/Nutrient Partition Approach," <u>Nutrition Reviews</u> , 49:33-45 (1991)	
	BRODERICK et al., "Human and Rat Amylin Have No Effects on Insulin Secretion in Isolated Rat Pancreatic Islets," <u>Biochem. Biophys. Res. Commun.</u> , 177(3):932-938 (1991)	
	BROWN et al., "The Effects of Amylin on Changes in Plasma Glucose and Gastric Emptying Following an Oral Glucose Load in Conscious Dogs," <u>Diabetes</u> , 43 (Suppl 1):172A (1994)	
	CHANCE et al., "Anorexia Following the Intrahypothalamic Administration of Amylin," <u>Brain Res.</u> , 539:352-354 (1991)	
	CHANCE et al., "Anorexia Following the Systemic Injection of Amylin," <u>Brain Res.</u> , 607:185-188 (1993)	
	CHANTRY et al., "Cross-Reactivity of Amylin with Calcitonin-Gene-Related Peptide Binding Sites in Rat Liver and Skeletal Muscle Membranes," <u>Biochem. J.</u> , 277:139-143 (1991)	
	COOPER et al., "The Amylin Superfamily: A Novel Grouping of Biologically Active Polypeptides Related to the Insulin A-Chain," <u>Prog. Growth Factor Research</u> , 1:99-105 (1989)	
	COOPER et al., "Amylin Found in Amyloid Deposits in Human Type 2 Diabetes Mellitus May Be a Hormone that Regulates Glycogen Metabolism in Skeletal Muscle," <u>Proc. Nat'l. Acad. Sci. USA</u> , 85:7763-7766 (1988)	
	COOPER et al., "Purification and Characterization of a Peptide from Amyloid-Rich Pancreases of Type 2 Diabetic Patients," <u>Proc. Nat'l. Acad. Sci. USA</u> , 84:8628-8632 (1987)	
	DEEMS et al., "Amylin or CGRP (8-37) Fragments Reverse Amylin-Induced Inhibition of ¹⁴ C-Glycogen Accumulation," <u>Biochem. Biophys. Res. Commun.</u> , 181(1):116-120 (1991)	
	FOLLETT et al., "Effect of Amylin on Insulin Receptor Kinase Activity In Vivo in the Rat," <u>Clin. Res.</u> , 39(1):39A (1991)	
	GAETA et al., "Amylin: A New Hormone as a Therapeutic Target in Diabetes Mellitus and Other Metabolic Diseases," <u>Med. Chem. Res.</u> , 3:483-490 (1994)	
	GALEAZZA et al., "Islet Amyloid Peptide (IAPP) Competes for Two Binding Sites Of CGRP," <u>Peptides</u> , 12:585-591 (1991)	
	GARDINER et al., "Antagonistic Effect of Human α -Calcitonin Gene-Related Peptide (8-37) on Regional Hemodynamic Actions of Rat Islet Amyloid Polypeptide in Conscious Long-Evans Rats," <u>Diabetes</u> , 40:948-951 (1991)	
	GEDULIN et al., "Amylin Secretion from the Perfused Pancreas: Dissociation from Insulin and Abnormal Elevation in Insulin-Resistant Diabetic Rats," <u>Biochem. Biophys. Res. Commun.</u> , 180(1):782-789 (1991)	
	GEDULIN et al., "Endogenous Amylin and Gastric Emptying in Rats: Comparison with GLP-1 And CCK-8," <u>Diabetologia</u> , 38 (Supp. 1):A244 (1995)	

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	08/870,762
Filing Date	June 6, 1997
First Named Inventor	Bradford J. Duft
Group Art Unit	1645
Examiner Name	Devi, S.
Attorney Docket Number	030639.0044.CPA2

Sheet	3	of	4
-------	---	----	---

	GOMEZ-FOIX et al., "Anti-Insulin Effects of Amylin and Calcitonin-Gen-Related Peptide on Hepatic Glycogen Metabolism," <u>Biochem J.</u> , 276:607-610 (1991)
	HUANG et al., "Hyperamylinemia, Hyperinsulinemia, and Insulin Resistance in Genetically Obese LA/N-cp Rats," <u>Hypertension</u> , 19:I-101-I-109 (1991)
	JUNG et al., "The Management of Obesity," <u>Clinical Endocrinology</u> , 35:11-20 (1991)
	KODA et al., "Amylin Concentrations and Glucose Control," <u>The Lancet</u> , 339:1179-1180 (1992)
	KOLTERMAN et al., "Effect of 14 Days' Subcutaneous Administration of the Human Amylin Analogue, Pramlintide (AC137), on an Intravenous Insulin Challenge and Response to a Standard Liquid Meal in Patients with IDDM," <u>Diabetologia</u> , 39(4):492-9 (1996)
	KOOPMANS et al., "Amylin-Induced In Vivo Insulin Resistance In Conscious Rats: The Liver Is More Sensitive To Amylin Than Peripheral Tissues," <u>Diabetologia</u> , 34:218-224 (1991)
	LEIGHTON et al., "Pancreatic Amylin and Calcitonin Gene-Related Peptide Cause Resistance to Insulin in Skeletal Muscle <i>In Vitro</i> ," <u>Nature</u> , 335(6191):632-635 (1988)
	LUDVIK et al., "Amylin: History and Overview," <u>Diabet. Med.</u> , 14:S9-S13 (1997)
	LUPIEN et al., "No Measurable Effect of Amylin on Lipolysis in Either White or Brown Isolated Adipocytes from Rats," <u>Diab. Nutr. Metab.</u> , 6(1):13-18 (1993)
	MACDONALD et al., "Infusion of the Human Amylin Analogue, AC137 Delays Gastric Emptying in Men with IDDM," <u>Diabetologia</u> , 38(Suppl 1):Abstract 118 (1995)
	MOLINA et al., "Induction of Insulin Resistance In Vivo by Amylin and Calcitonin Gene-Related Peptide," <u>Diabetes</u> , 39:260-265 (1990)
	MOORE et al., "Co-Secretion of Amylin and Insulin from Cultured Islet β -Cells: Modulation by Nutrient Secretagogues, Islet Hormones and Hypoglycemic Agents," <u>Biochem. Biophys. Res. Commun.</u> , 179(1):1-9 (1991)
	MORLEY et al., "Effects of Amylin on Appetite Regulation and Memory," <u>Can. J. Physiol. Pharm.</u> , 73(7):1042-6 (1995)
	NOWAK et al., "Accelerated Gastric Emptying in Diabetic Rodents: Effect of Insulin Treatment and Pancreas Transplantation," <u>J. Lab. Clin. Med.</u> , 123(1):110-6 (1994)
	PITTNER et al., "Amylin and Epinephrine Have No Direct Effect on Glucose Transport in Isolated Rat Soleus Muscle," <u>FEBS Letts.</u> , 365(1):98-100 (1995)
	PITTNER et al., "Molecular Physiology of Amylin," <u>J. Cell. Biochem.</u> , 55S:19-28 (1994)
	PLOURDE et al., "CGRP 8-27 Blocks the Inhibition of Gastric Emptying Induced by Intravenous Injection of α -CGRP in Rats," <u>Life Sci.</u> , 52:857-862 (1993)
	RINK et al., "Structure and Biology of Amylin," <u>TIPS</u> , 14:113-118 (1993)
	RODEN et al., "Effect of Islet Amyloid Polypeptide on Hepatic Insulin Resistance and Glucose Production in the Isolated Perfused Rat Liver," <u>Diabetologia</u> , 35:116-120 (1992)
	ROSENBLOOM et al., "Chronic Overtreatment with Insulin in Children and Adolescents," <u>Am. J. Dis. Child.</u> , 131(8):881-5 (1977)
	SHULUTKO (Ed.), <u>Physician's Handbook</u> , St. Petersburg, p. 496 (1996)
	STEPHENS et al., "Presence of Liver CGRP/Amylin Receptors in Only Nonparenchymal Cells and Absence of Direct Regulation of Rat Liver Glucose Metabolism by CGRP/Amylin," <u>Diabetes</u> , 40:395-400 (1991)

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Sheet	4	of	4
Application Number	08/870,762		
Filing Date	June 6, 1997		
First Named Inventor	Bradford J. Duft		
Group Art Unit	1645		
Examiner Name	Devi, S.		
Attorney Docket Number	030639.0044.CPA2		

		STARKOVA (Ed.), <u>Clinical Endocrinology</u> , Moscow, Meditsina, p. 197 (1991)	
		WANG et al., " ⁸⁻³⁷ h-CGRP Antagonizes Actions of Amylin on Carbohydrate Metabolism In Vitro And In Vivo," <u>FEBS Letts.</u> , 291(2):195-198 (1991)	
		YOUNG et al., "Amylin and Insulin in Rat Soleus Muscle: Dose Responses for Cosecreted Noncompetitive Antagonists," <u>Am. J. Phys.</u> , 263(2):E274-E281 (1992)	
		YOUNG et al., "Effects of Amylin on Glucose Metabolism and Glycogenolysis In Vivo and In Vitro," <u>Am. J. Physiol.</u> , 259:E457-E461 (1990)	
		YOUNG et al., "Gastric Emptying Is Accelerated in Diabetic BB Rats and Is Slowed by Subcutaneous Injections of Amylin," <u>Diabetologia</u> , 38(6):642-648 (1995)	
		YOUNG et al., "Amylin Activates Glycogen Phosphorylase in the Isolated Soleus Muscle of the Rat," <u>FEBS Letts.</u> , 281(1,2):149-151 (1991)	
		YOUNG et al., " ⁸⁻³⁷ hCGRP, an Amylin Receptor Antagonist, Enhances the Insulin Response and Perturbs the Glucose Response to Infused Arginine in Anesthetized Rats," <u>Mol. Cell Endocrino.</u> , 84:R1-R5 (1992)	
		ZAIDI et al., "Amylin in Bone Conservation: Current Evidence and Hypothetical Considerations," <u>TEM</u> , 4(8):255-259 (1993)	
		ZHU et al., "Amylin Increases Cyclic Amp Formation in L6 Myocytes through Calcitonin Gene-Related Peptide Receptors," <u>Biochem. Biophys. Res. Commun.</u> , 177(2):771-776 (1991)	